Response to Office Action Mailed June 27, 2008

A. Claims In The Case

Claim 1 has been rejected. Claims 2-15, 17-19, 28 and 30 have been withdrawn. Claim 1 has been amended. Claims 1-15, 17-19, 28, and 30 are pending in the case.

B. Election/Restriction

Applicant acknowledges the withdrawal of claims 2-25, 17-19, 28, and 30. Applicant requests the Examiner to consider rejoinder of the withdrawn claims if the generic independent claim is found to be allowable.

C. The Claims Are Not Anticipated By The Cited Art Pursuant To 35 U.S.C. § 102

The Examiner rejected claim 1 as being anticipated by U.S. Patent No. 4,946,685 to Edgren ("Edgren"). Applicant respectfully disagrees with these rejections.

The standard for "anticipation" is one of fairly strict identity. A claim can only be anticipated if each and every element set forth in the claims is found to be either expressly or inherently described in the cited art. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 728, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131.

Claim 1 describes a combination of features including but not limited to the feature of "a matrix core comprising a therapeutically effective amount of a first drug, wherein the matrix core allows sustained release of the first drug." The Office Action appears to equate the "matrix core" with laminate layer 13 of the embodiment of Edgren depicted in FIG. 3. Applicant submits that

laminate layer 13 does not allow "sustained release of the first drug." Instead laminate layer 13 of Edgren appears to be an instant release layer. For example, Edgren states:

> For example, the bilaminated structure of dosage form 10 comprises a fast drug releasing lamina 13, and a slower drug releasing lamina 12. The fast drug releasing lamina 13 begins to dispense drug 14 immediately for producing an initial plasma concentration of drug 14 in a warm-blooded animal, which expression includes humans.
> (Edgren, Col. 14, lines 54-60)

> In FIG. 3, dosage form 10 comprises optional drug 16 in coat 15. The presence of drug 16 provides instant drug release when dosage form 10 is introduced into an aqueous environment of use. The instant drug 16 is supplemental to the instant and prolonged drug delivery of dosage form 10, for improved drug therapy.
> (Edgren, Col. 7, lines 31-37)

As noted above, Edgren appears to be directed to a dosage from that provides "instant and prolonged drug delivery" which may be further coated with an instant drug release coating. Thus, Edgren appears to teach a dosage form that includes two instant release layers and a sustained release layer. In contrast, Applicant's claimed dosage form includes two sustained release layers (matrix core layer and first layer) and an immediate release layer (second layer). Applicant submits that Edgren does not appear to teach or suggest these features.

D. Summary

Based on the above, Applicant submits that all claims are now in condition for allowance. Favorable reconsideration is respectfully requested.

If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees are inadvertently omitted or if any additional fees are required or have been overpaid, please appropriately charge or credit those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/6165-10702/EBM

Respectfully submitted,

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